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(54) **ARTICULABLE ANCHOR**

(75) Inventors: **James Kutsko**, Carnation, WA (US);  
**Seung Yi**, Aliso Viejo, CA (US); **Clinton Lee Finger**, Bellevue, WA (US)

(73) Assignee: **Spiration, Inc.**, Redmond, WA (US)

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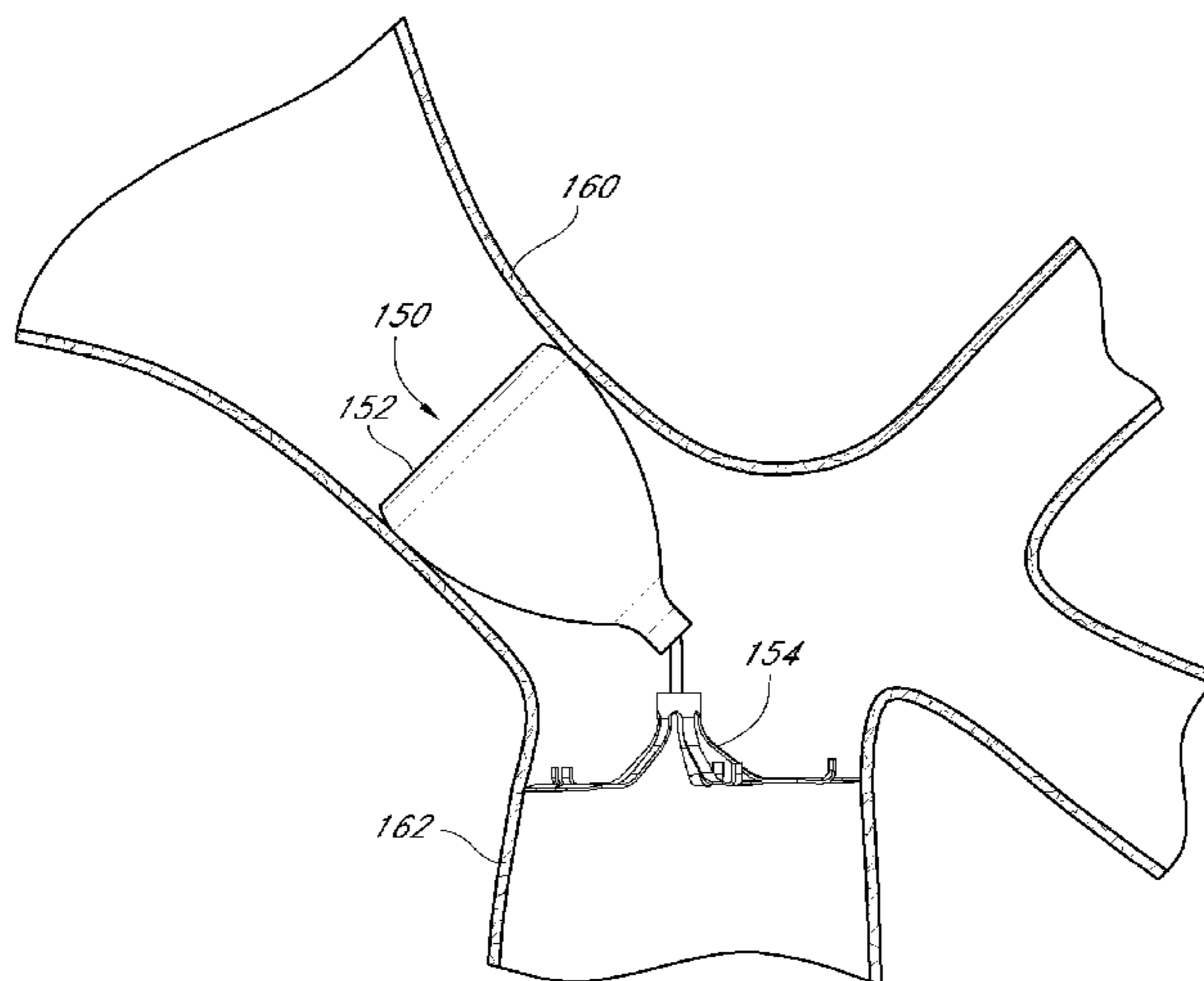
*Primary Examiner* — Suzette J Gherbi

(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear LLP

(57) **ABSTRACT**

Embodiments disclosed herein relate to devices implantable into a human lung, for example to reduce the volume of air trapped in a diseased portion of the lung to prevent inhalation while permitting expiration out of the diseased portion. In some embodiments, the device comprises a distal portion with an anchor system that may anchor the device into tissue of an air passageway wall, and the distal portion may be connected to a proximal portion via a flexible portion that permits the distal portion to articulate substantially with respect to the proximal portion, such that the distal portion and the proximal portion may be non-collinear along a longitudinal axis of the distal portion. This may facilitate implantation of the device into a non-linear air passageway.

**34 Claims, 11 Drawing Sheets**



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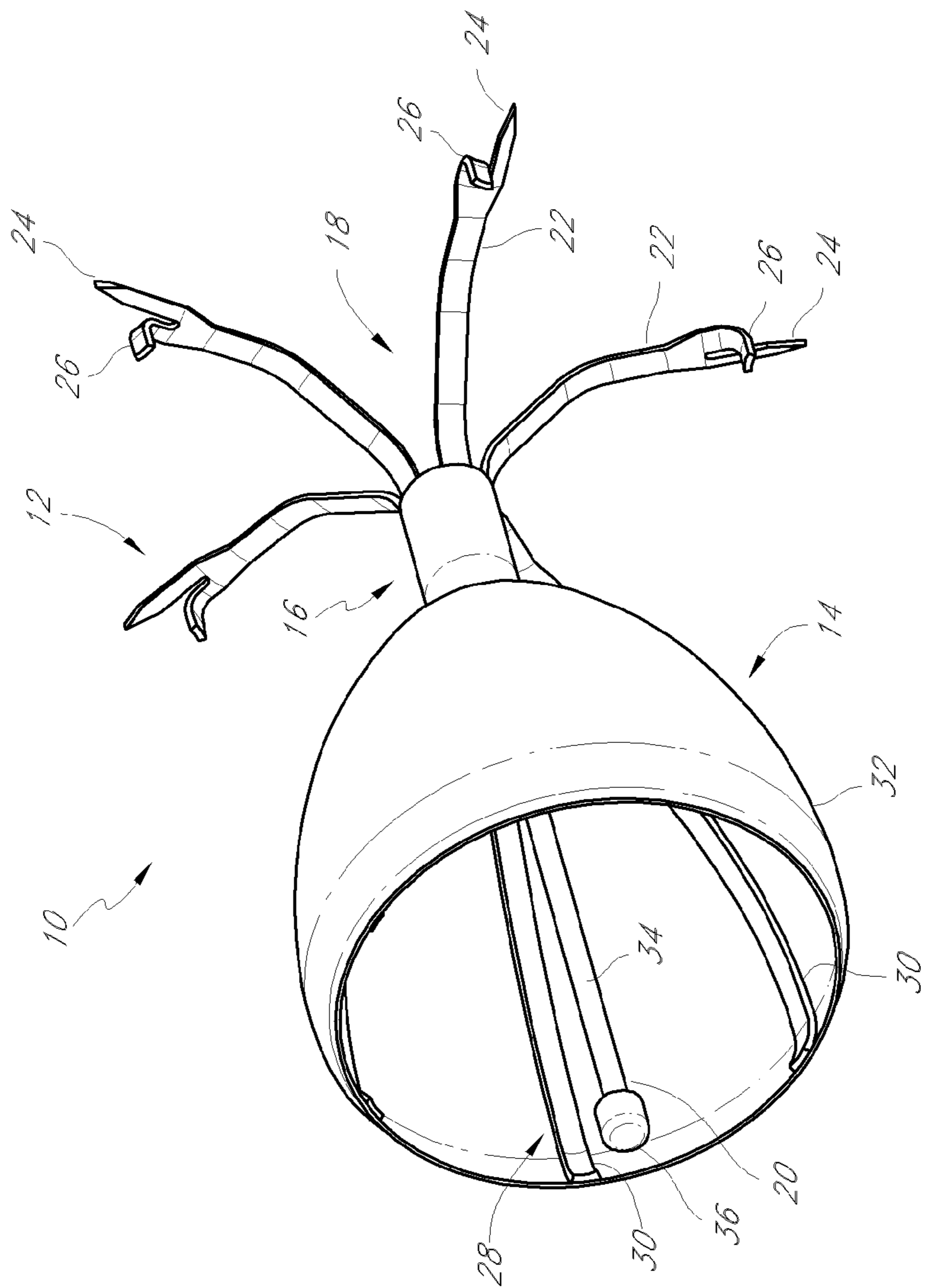


FIG. 1



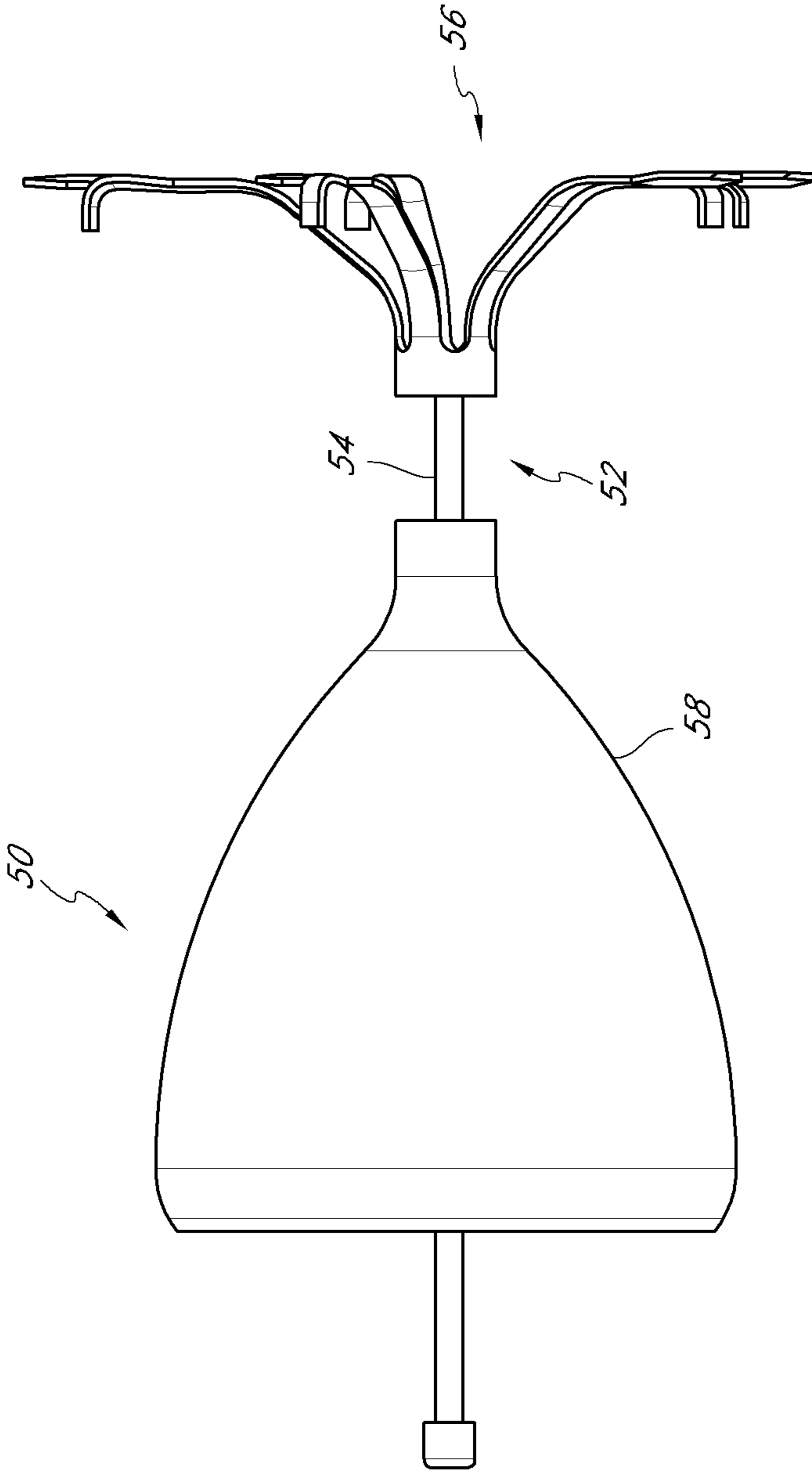


FIG. 2

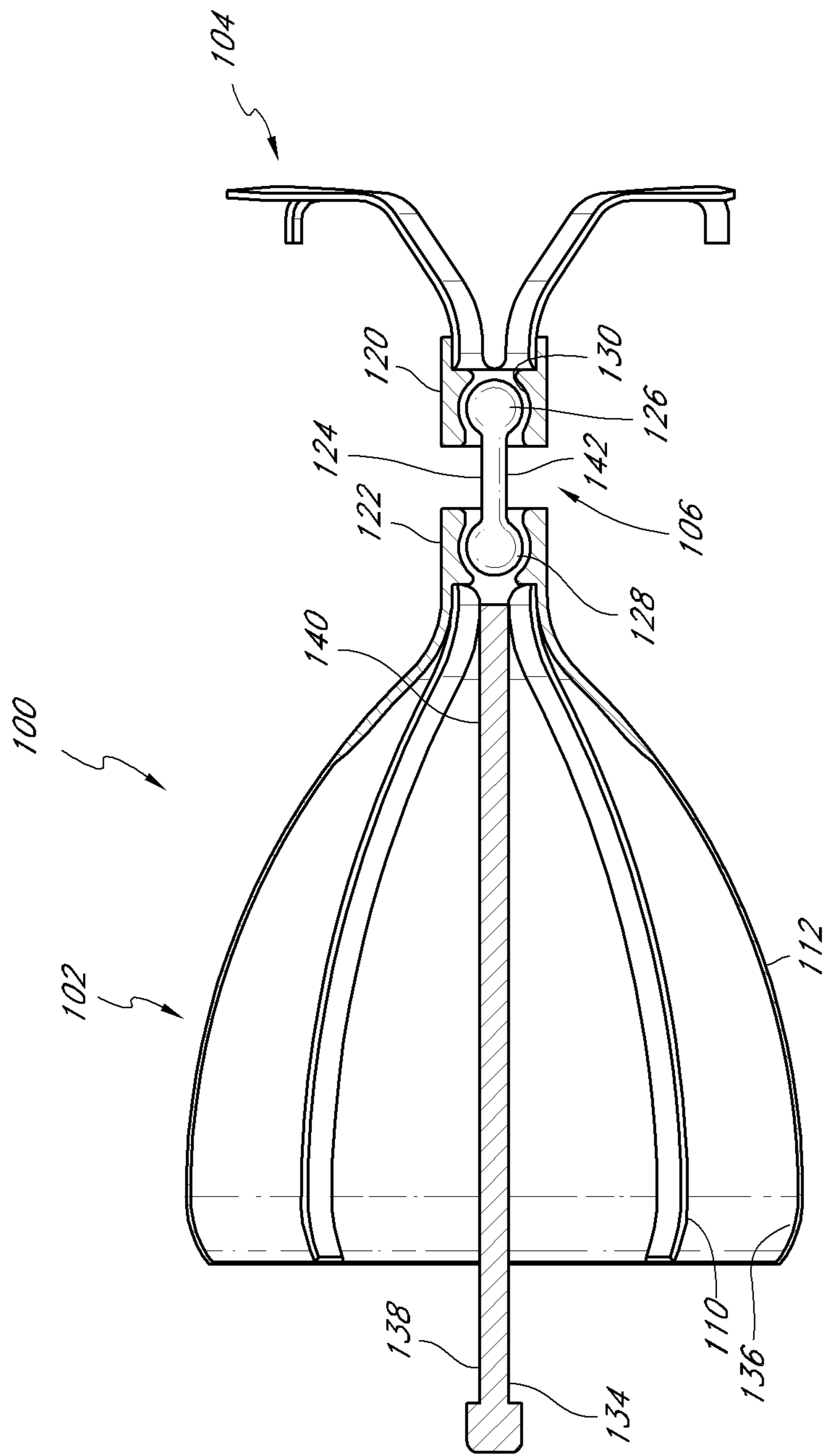


FIG. 3

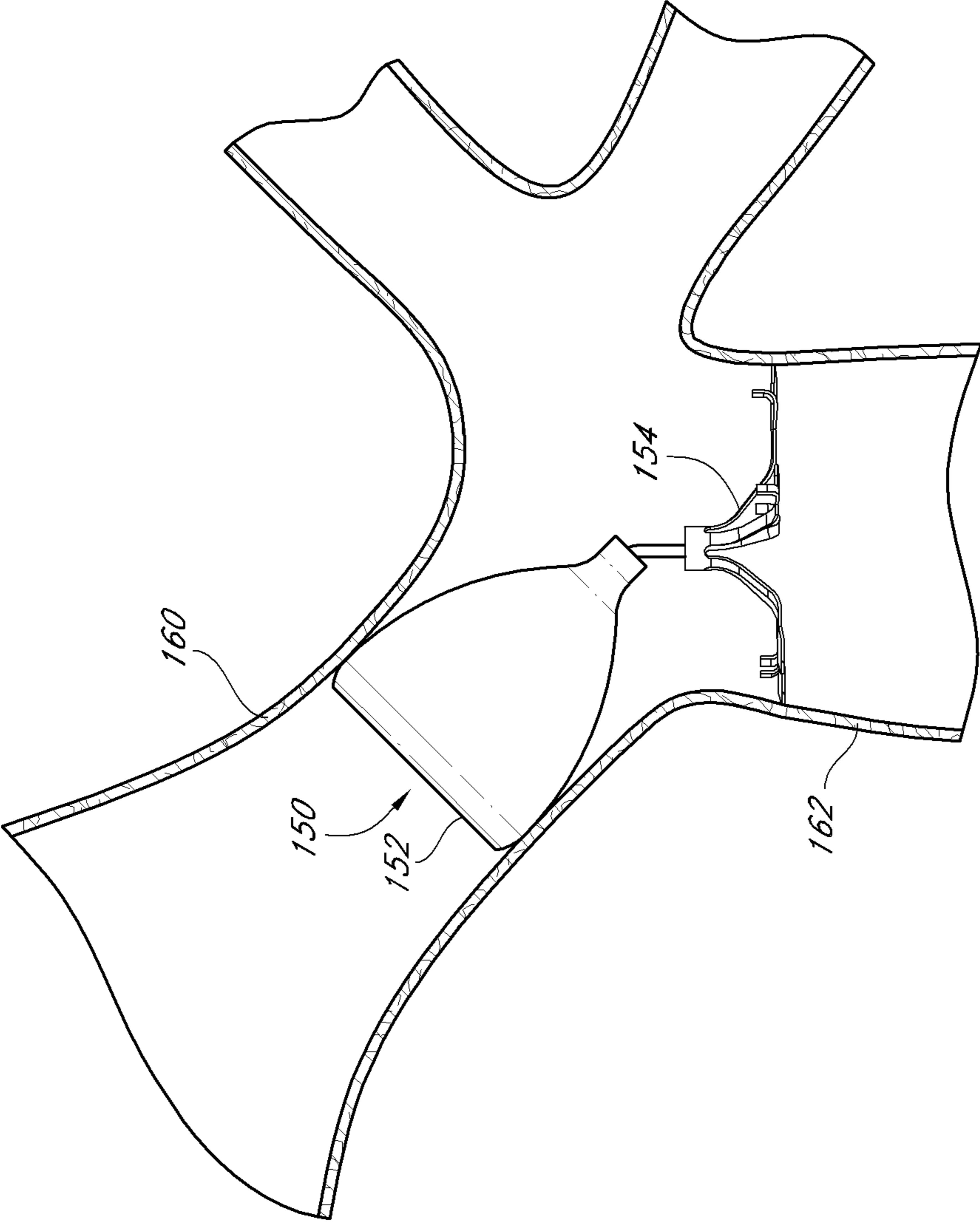


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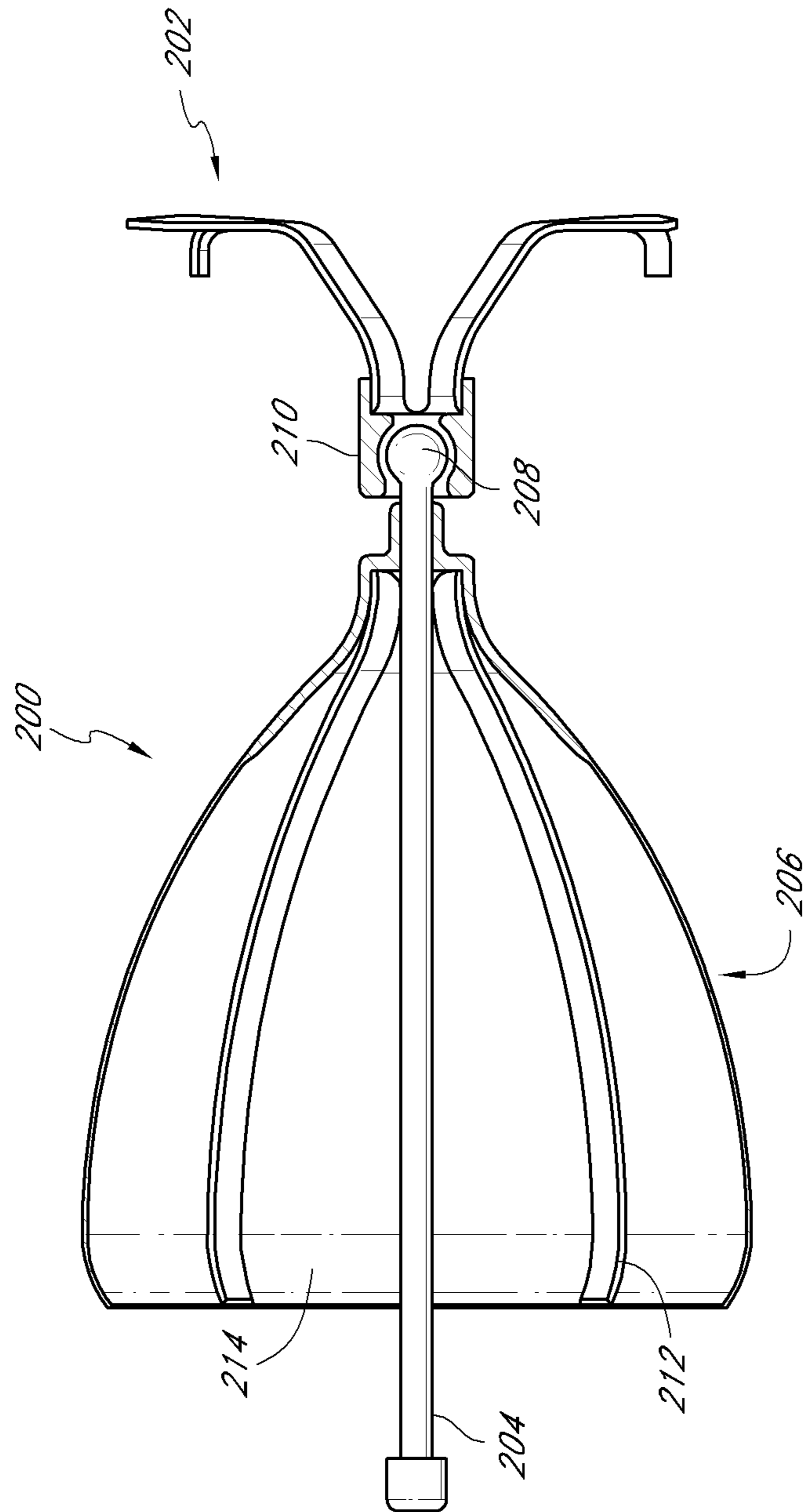


FIG. 5

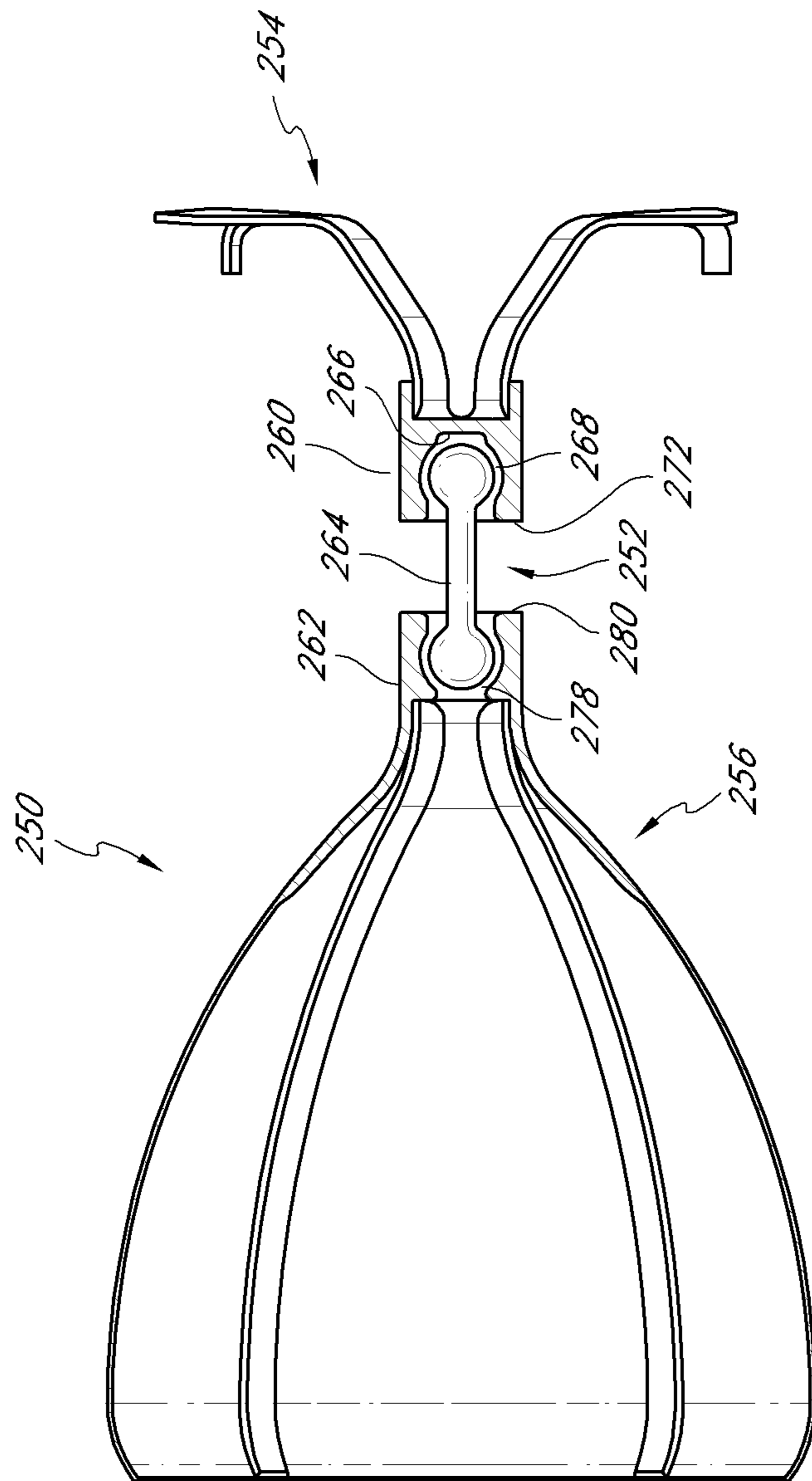


FIG. 6

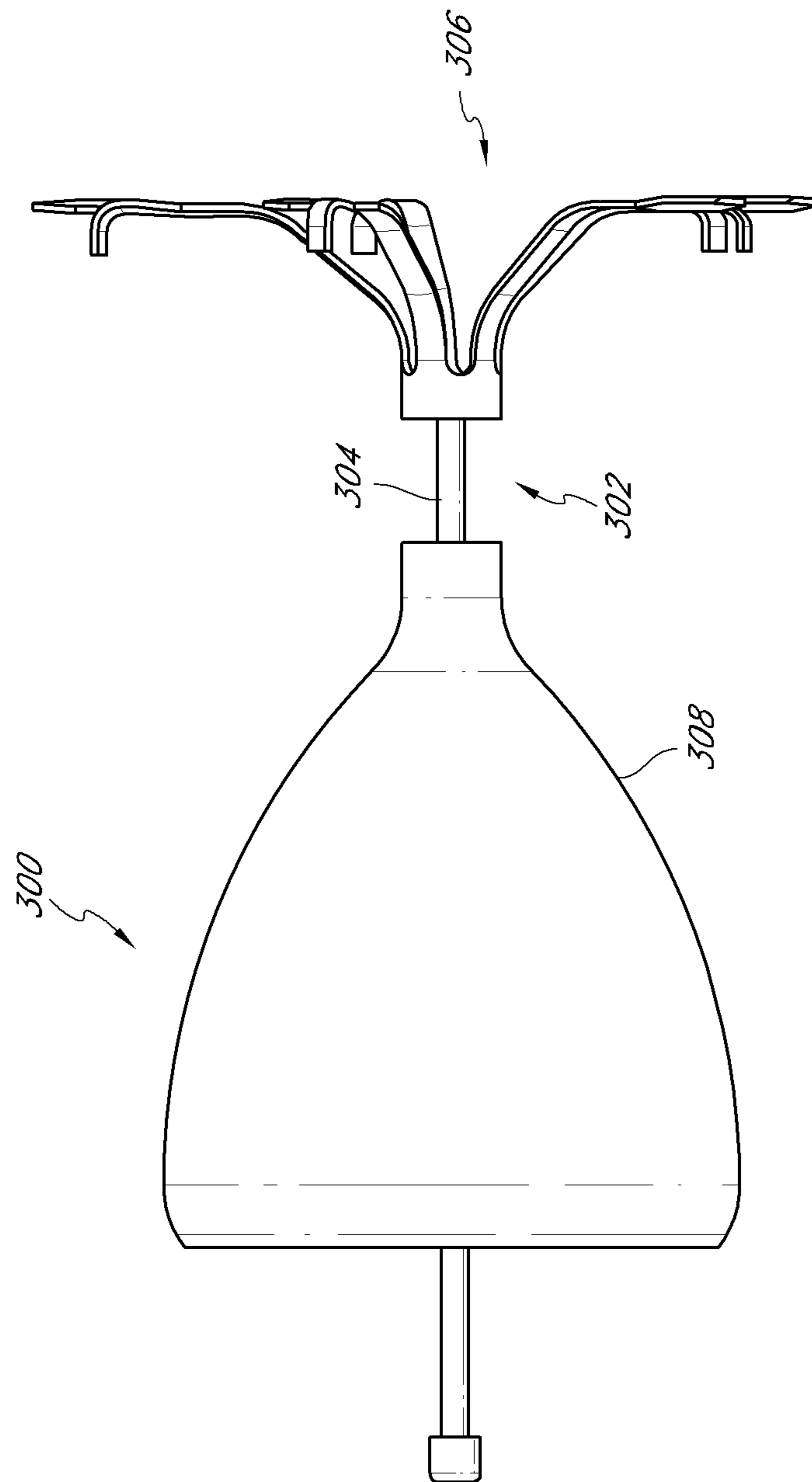


FIG. 7

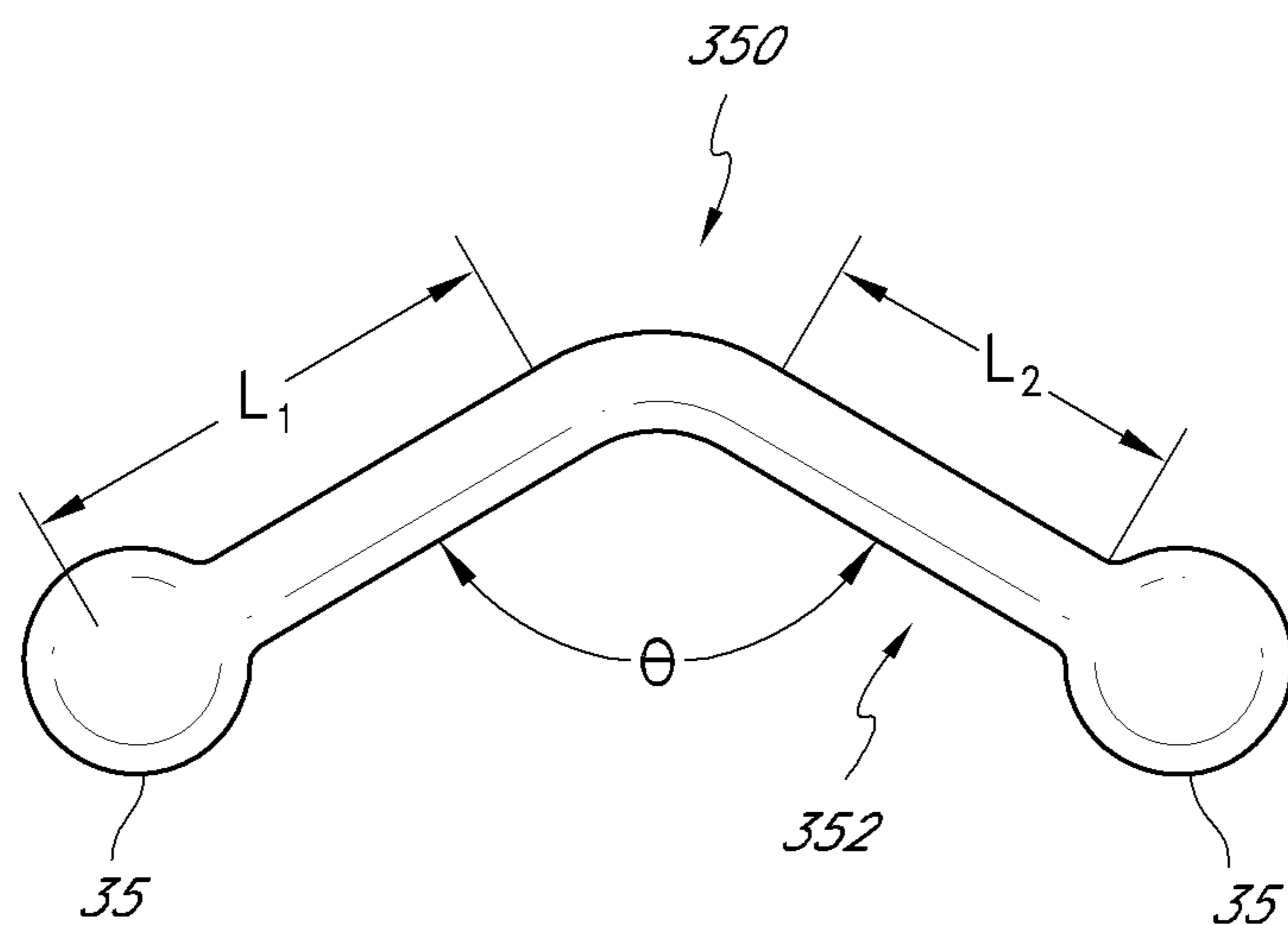


FIG. 8

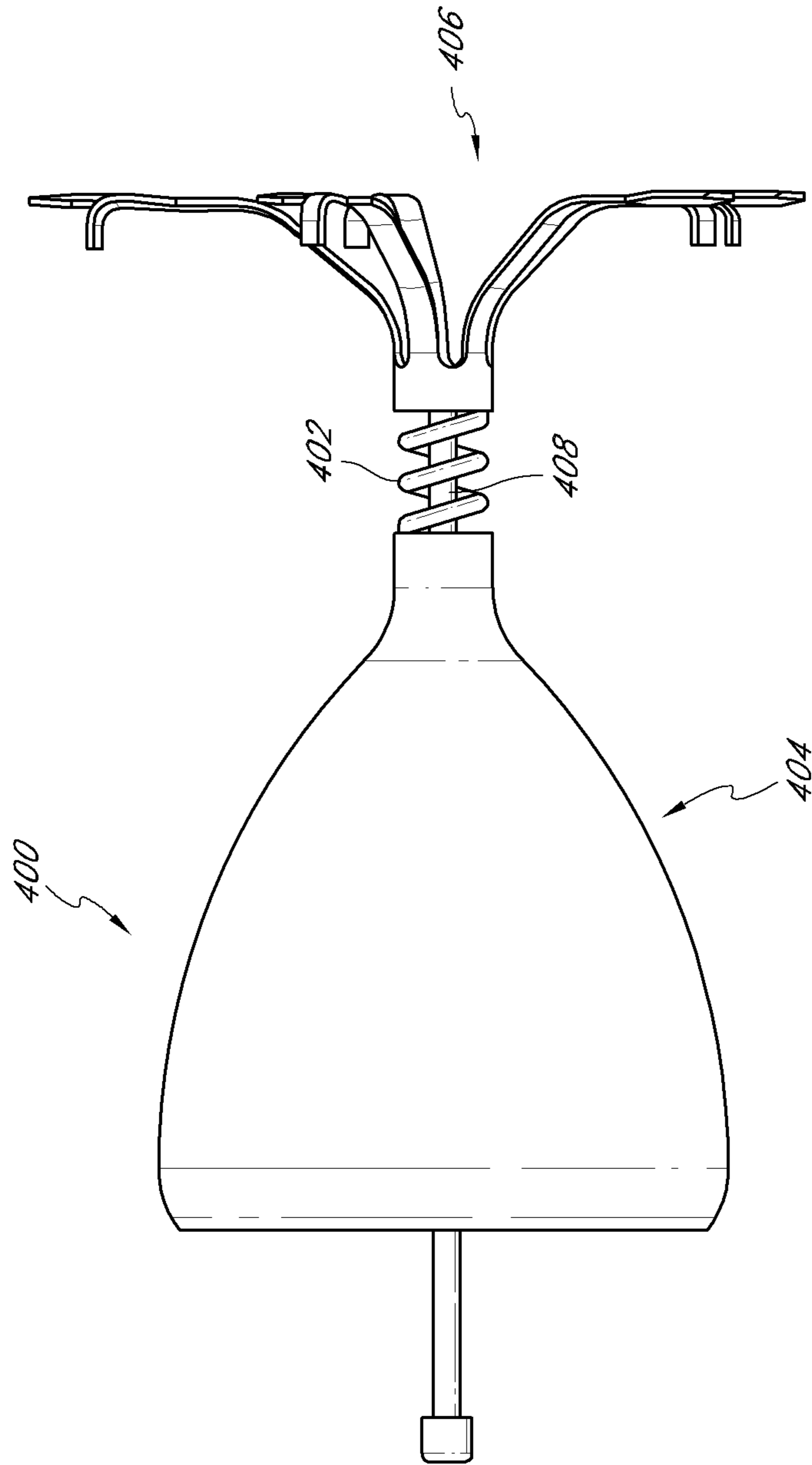
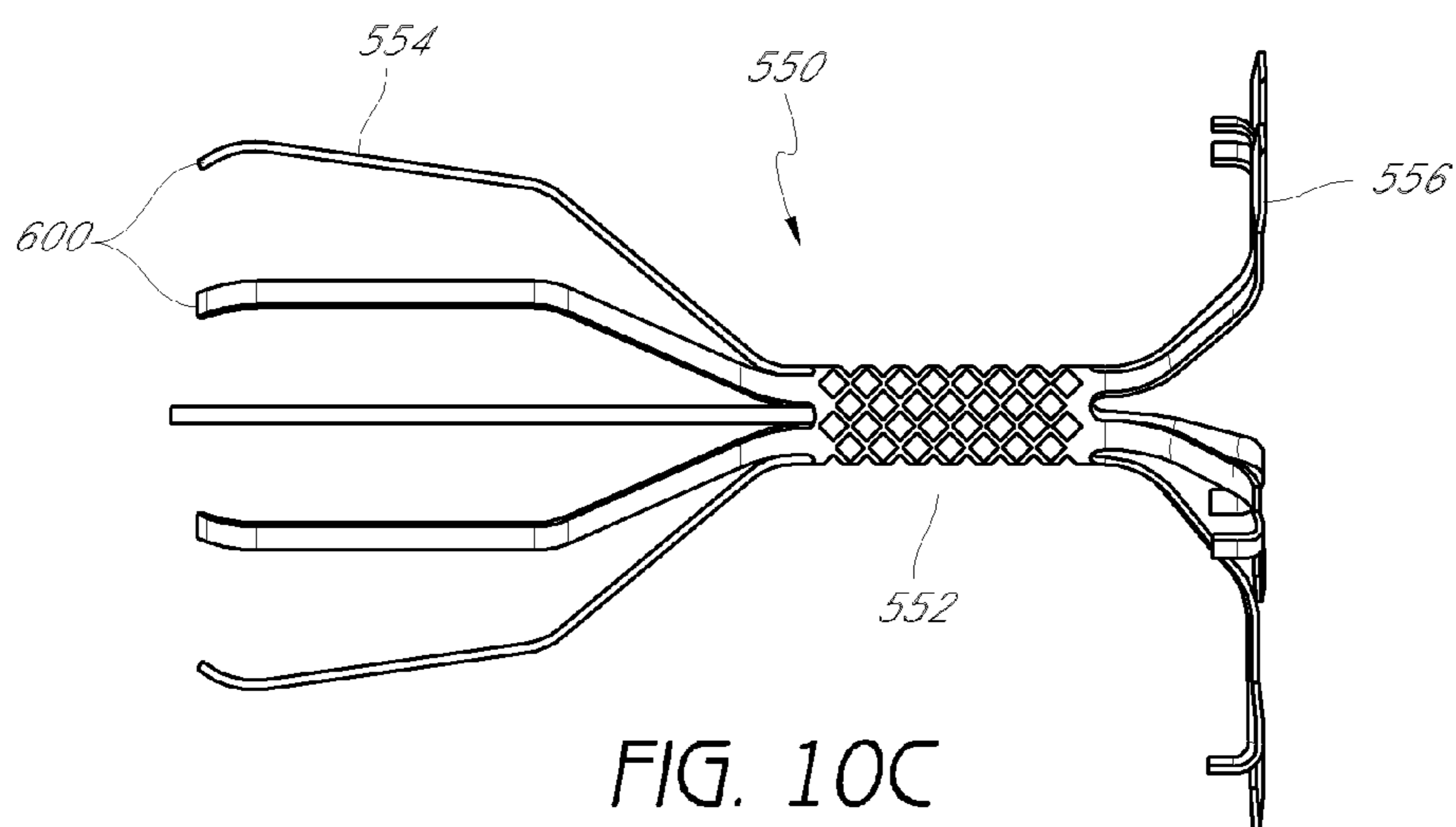
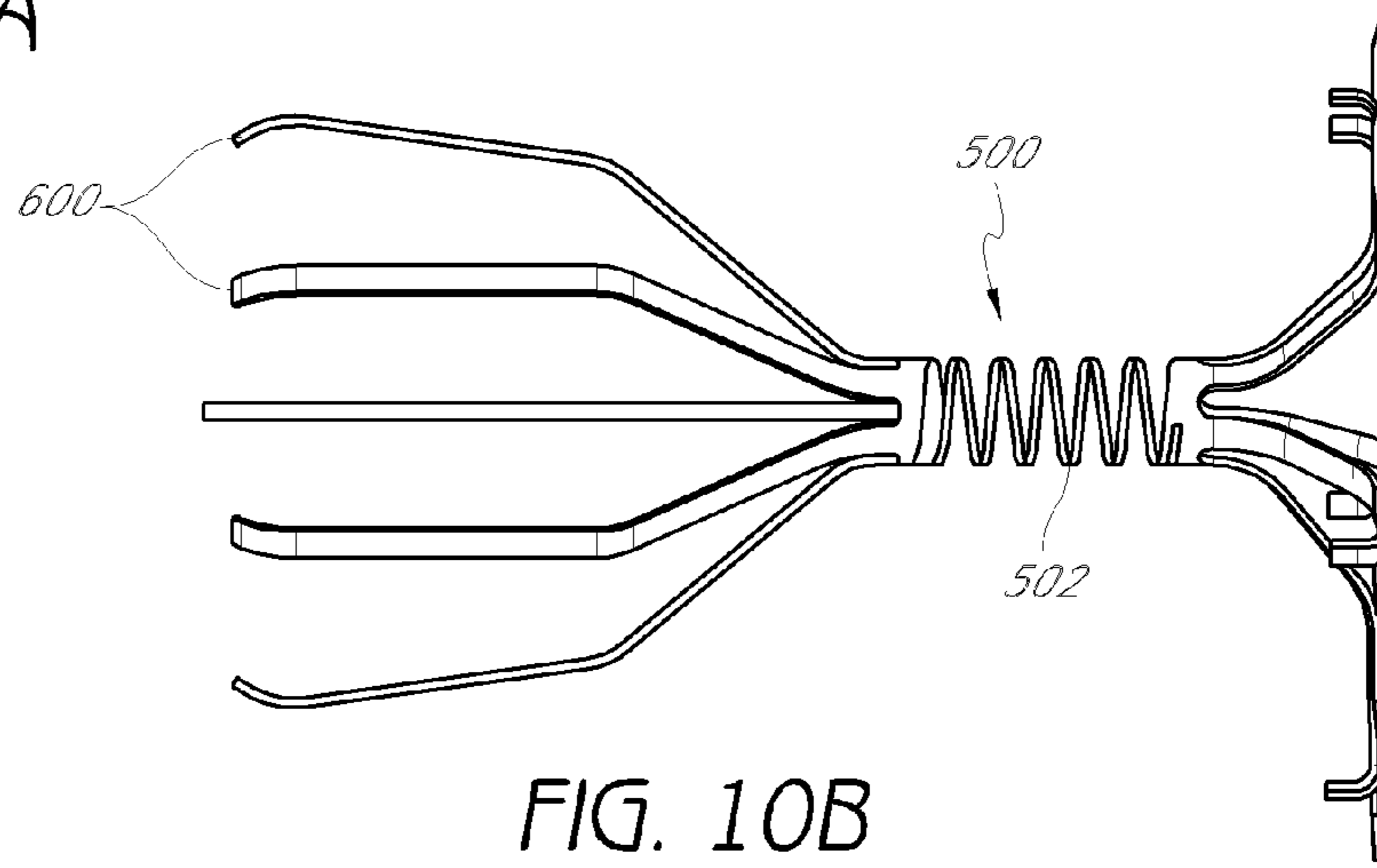
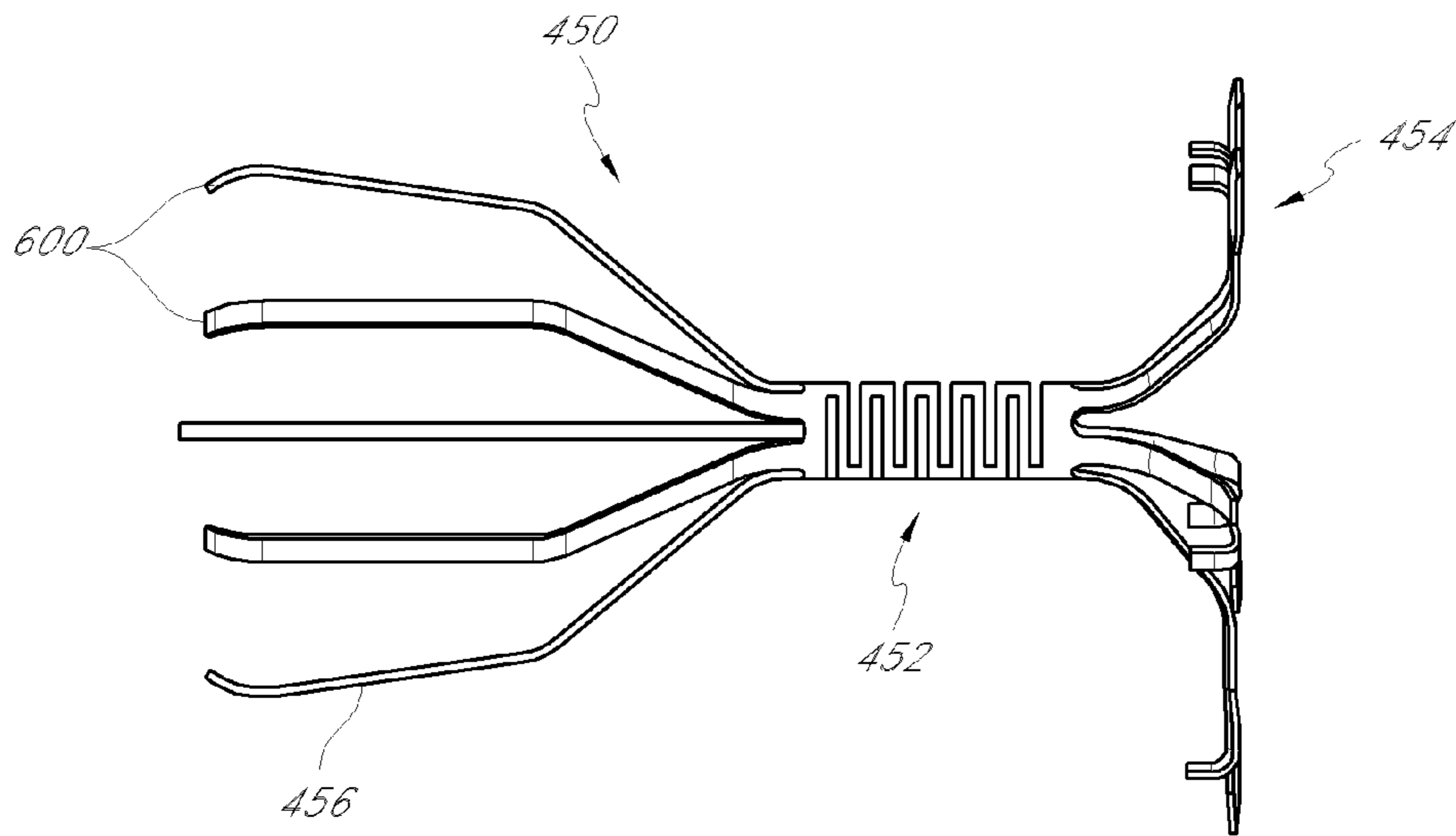


FIG. 9





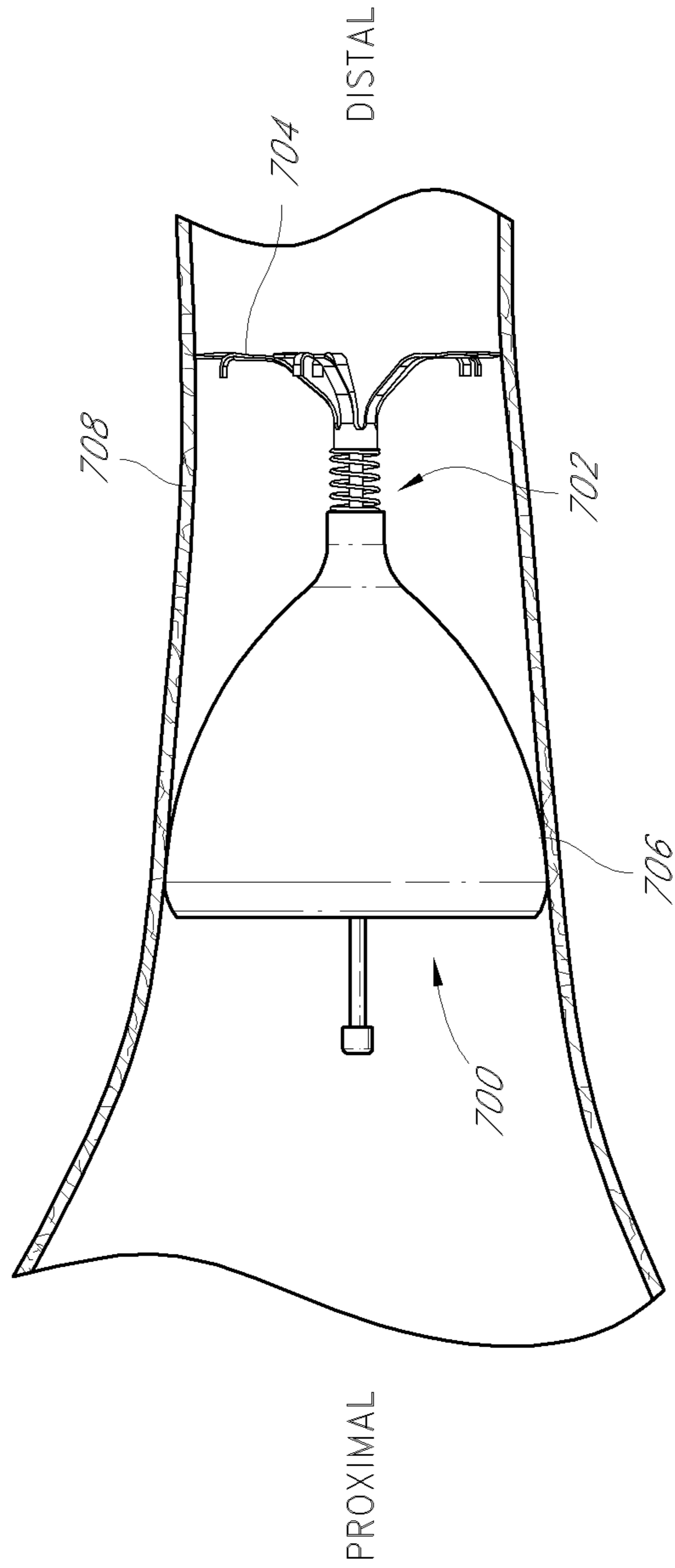


FIG. 11

**ARTICULABLE ANCHOR**

## RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/754,394, filed Apr. 5, 2010, which is a continuation of U.S. application Ser. No. 11/585,415, filed Oct. 24, 2006, now issued as U.S. Pat. No. 7,691,151, which claims the benefit under 35 U.S.C. 119(c) to U.S. Provisional Patent Application No. 60/787,995, filed Mar. 31, 2006. The foregoing applications are hereby incorporated by reference in their entirety.

## BACKGROUND OF THE INVENTION

## 1. Field of the Invention

The inventions relate in general to the field of pulmonary treatments, and specifically to systems, devices, and methods for treating a patient's lung or portion thereof.

## 2. Description of the Related Art

Chronic Obstructive Pulmonary Disease ("COPD") has become a major cause of morbidity and mortality in the United States. COPD is typically characterized by the presence of airflow obstructions due to chronic bronchitis or emphysema. The airflow obstructions in COPD are due largely to structural abnormalities in the smaller airways in the lungs.

Mortality, health-related costs, and the segment of the population having adverse effects due to COPD are substantial. COPD is a progressive disease that can severely affect a person's ability to accomplish normal tasks. One method of treating COPD is the insertion of one-way valves into lumens in the lung. The valves inhibit inhalation, but permit exhalation of air already within the lung. The lung presents challenge in mounting such valves because lumens within it are rarely linear over a useful distance. Accordingly, there is a need for a device to permit mounting of valves within non-linear lumens in the lung.

## SUMMARY OF THE INVENTION

Accordingly, one aspect of the invention comprises an implantable device for providing substantially one-way flow of air through a lumen in a human lung to reduce the volume of air trapped in a diseased portion of the lung. The implantable device occludes the lumen to substantially prevent inhalation while substantially permitting expiration out of said diseased portion of the lung. The implantable device is deployable into the lumen with a catheter.

One aspect of an embodiment of the implantable device can comprise a one-way valve being generally umbrella-shaped in configuration. The valve is collapsible for containment within a delivery catheter and expandable in situ when deployed. The valve substantially occludes the lumen. The valve is configured so that when deployed in an orientation to substantially preclude inhalation, inhaled air is prevented from flowing past the valve into said lung by capturing said air within the umbrella-shaped valve. The air exerts an outward force on the umbrella shape and forces said valve to tightly engage the lumen. The valve is configured to permit expiration to occur between the perimeter of the valve and the lumen.

The valve also defines a longitudinal axis and comprises a plurality of metal struts that define a generally bell-shaped frame. Each of the struts have a first end that curves slightly inward towards the longitudinal axis of said implantable device when deployed and a second end proximal a junction

of the second ends of the other struts. The valve also has a resilient membrane that wraps around at least a part of the metal struts and is supported by them. The membrane extends from the junction of the plurality of metal struts toward the first end of said struts. The valve also comprises a central post with a first part that extends within the membrane from the junction of said plurality of metal struts at the center of the bell-shaped frame. The post has a flange at an end distal from the strut junction. The flange is configured to permit deployment, positioning, and recapture of said implantable device. The central post further comprises a second part that extends axially outside the membrane.

Another aspect of the invention comprises an anchor for securing the implantable device within the lumen by inhibiting migration of the device once deployed. The anchor comprises a plurality of resilient arms extending outwardly and radially from the second part of the central post. Each of said arms are configured so as to be collapsible for containment within a delivery catheter and expandable to engage the lumen when deployed in situ. Each of the arms comprises a generally tapered distal end to permit the arm to penetrate the wall of the lumen. The arms further comprise a planar member proximal the tapered distal end and positioned at an angle to the arm to limit advancement of said arm into the lumen wall by contacting the surface of said lumen wall.

Another aspect of the invention comprises a mechanism connecting the one-way valve to the anchor and being disposed generally along the longitudinal axis when the device is in a collapsed state. The mechanism is configured to permit the valve to be oriented at an angle to the anchor when deployed, thereby allowing the anchor to be positioned in a section of the lumen that is at an angle to a section of said lumen in which the one-way valve is positioned. The mechanism comprises at least one connector at a first end to connect the mechanism to the valve. In some embodiments, the mechanism comprises a flexible member configured to be articulable to permit angled orientation of the anchor. In some embodiments, the flexible member comprises a helical spring. In some embodiments, the flexible member comprises a generally cylindrical mesh.

In some embodiments of the connector, a second end of the mechanism comprises a generally spherical connector. In some embodiments, the second end of the mechanism resides in a cavity within the anchor. In some embodiments the cavity is elongated. In some embodiments, the first end of the mechanism comprises a generally spherical connector.

In some embodiments, a cavity is within the anchor, wherein the first end of the mechanism can reside. In some embodiments, the implantable device comprises a second end of the mechanism which comprises a generally spherical connector. In some embodiments, the second end of the mechanism resides in a cavity within the valve. In some embodiments, at least one of the cavities is elongated.

Another aspect of an embodiment is an implantable device for deployment in an anatomical lumen wherein the device comprises an occluding device and an articulable anchor for securing the occluding device within the lumen in a manner that permits the anchor to articulate substantially with respect to said occluding device. The articulable anchor comprises a mechanism connecting said anchor to the occluding device. Additionally, the mechanism comprises at least one connector at a first end to connect said mechanism to at least one anchoring member and the articulable anchor includes a cavity.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an implantable device with a one-way valve, an anchor, and a connector;

FIG. 2 is a side view of an implantable device with an articuable anchor.

FIG. 3 is a cross-sectional view of the device of FIG. 2.

FIG. 4 is a cross-sectional view of an air passageway and an implantable device with an articuable anchor that spans a bifurcated air passageway;

FIG. 5 is a cross-sectional view of an implantable device with an articuable anchor in accordance with another embodiment;

FIG. 6 is a cross-sectional view of an implantable device with an articuable anchor in accordance with another embodiment;

FIG. 7 is a side view of an implantable device with an articuable anchor in accordance with another embodiment;

FIG. 8 is a side view of a flexible connector for use in an implantable device with an articuable anchor;

FIG. 9 is a side view of an implantable device with an articuable anchor having a biasing member and a connector positioned between an obstruction member and the anchor system;

FIGS. 10A-10C are side views of alternative embodiments of frames for implantable devices with articuable members embodied as flexible connectors; and

FIG. 11 is a cross-sectional view of an air passageway and a flexible implantable device positioned in the air passageway

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 illustrates an implantable device in an expanded position. The implantable device 10 is configured to affect airflow in an air passageway in a lung. The implantable device comprises an anchor 12 and an obstruction member 14. A connecting mechanism 16 couples the anchor 12 to the obstruction member 14. The illustrated implantable device 10 includes a support structure 18 that can form the frame of the implantable device 10. At least a portion of the anchor 12, the connecting mechanism 16, and the obstruction member 14 can be formed by the support structure 18. An elongated member 20 extends axially through obstruction member 14 and can be directly or indirectly coupled to the support structure 18.

The obstruction member 14 surrounds at least a portion of the elongated member 20 and is configured to interact with an anatomical lumen, such as an air passageway, to regulate the flow of fluid through the lumen. The obstruction member 14 can effectively function as a one-way valve. One example of an obstruction member is an occluding device.

The anchor 12 comprises a plurality of anchor members 22 that extend from the connecting mechanism 16. In the illustrated embodiment, each of the anchor members 22 is an elongated member that extends radially outward from the connecting mechanism 16 and terminates at a piercing end 24, although the anchor members 22 can have any number of piercing ends. One or more stops 26 can be positioned along each anchor member 22, preferably positioned at some point near the piercing members 24. The stops 26 can be configured to limit the puncturing by the piercing member 24 through lung tissue beyond a desired depth.

The stops 26 can be formed by splitting the distal ends of the anchor members 22. One of the split sections can be bent downwardly to form the stop 26, while leaving the second split section to extend outwardly to form the piercing member

24. Although the stops 26 can be formed integrally with the anchor member 22, the stops 26 can also be applied in a subsequent process. For example, each stop 26 can be a piece of metal that is mounted to the anchor members 22. Thus, each of the anchor members 22 can be of a one piece or multi-piece construction.

Any number of anchor members 22 can be used to limit migration of the implantable device 10 implanted at a desired deployment site. The illustrated implantable device 10 comprises five anchor members 22 that are coupled to the connecting mechanism 16. However, the anchor 12 can comprise any suitable number of anchor members in any various configurations. A skilled artisan can select the number of anchor members 22 based on the size of an air passageway, anchor design, and the like. The anchor members 22 can be positioned at regular or irregular intervals. When the anchor 12 is positioned in situ, the piercing members 24 can engage tissue of an air passageway wall of a lung to retain the implantable device 10 at a desired location. One non-limiting example of such an engagement occurs when at least one piercing member punctures the wall of the air passageway.

With continued reference to FIG. 1, the obstruction member 14 is generally umbrella-shaped and comprises an obstructing member frame 28 that carries a membrane 32. The obstructing frame 28 includes a plurality of arcuate struts 30 that support the membrane 32.

A plurality of pathways can be defined by the obstruction member 14 between each pair of struts 30. When the implantable device 10 is securely anchored in a lung passageway, the struts 30 can bias the obstruction member 14 outwardly against the air passageway wall. Between each pair of struts 30, the membrane 32 can define the pathway that permits mucus transport past the obstruction member 14 through the associated air passageway.

Proper mucociliary functioning can be maintained to ensure that the respiratory system continues to self clean after an implantable device has been deployed. To maintain mucociliary transport the membrane 32 can be folded inwardly away from the air passageway wall, especially during exhalation when the implantable device 10 has the anchor 12 positioned distally. The membrane 32 can press lightly against the air passageway wall in order to permit ciliary action for the movement of mucus past the membrane 32. Of course, the implantable device can have other configurations that permit mucus transport.

The membrane 32 can be treated to enhance sealing, improve biostability, and/or enhance mucus transport. To enhance valving action, the membrane 32 can be treated with a material that interacts with a wall of an air passageway to improve functioning. A coating on the membrane can reduce airflow in at least one direction between the air passageway and the expanded membrane engaging the air passageway wall. The coating can be a hydrogel that helps the membrane 32 adhere to the air passageway wall to further limit air flow past the implantable device in at least one direction. Other coating materials can be applied to the membrane or other portions of the implantable device depending on the intended application. The coating can be applied before, during, or after the implantable device is placed in a passageway.

In some embodiments, the membrane 32 can be coated with a lubricious material to limit adherence to an air passageway. Additionally, an implantable device may partially or fully collapse when subjected to rapid pressure changes, such as when a person coughs. If the membrane is folded together, the lubricious material can inhibit sticking of the membrane to itself so that the implantable device can quickly re-expand to function effectively again.

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The implantable device can be adapted to facilitated movement through a delivery lumen. To reduce frictional forces between the implantable device and a lumen of a delivery instrument, a release agent can be applied to the implantable device. The release agent can reduce the force required to eject the implantable device out of the lumen as detailed above.

The struts can have first strut ends connected to the connecting mechanism 16 and opposing second strut ends. The proximal tips of the struts can curve radially inward toward the longitudinal axis of the implantable device 10.

With continued reference to FIG. 1, the elongated member 20 comprises a rod 34 that is connected to the connecting mechanism 16 and a gripping head 36. The rod 34 is a generally cylindrical body that extends along the longitudinal axis of the implantable device 10, although the rod 34 can be at other suitable locations. For example, the rod 34 can be angled or offset from the longitudinal axial of the implantable device 10.

The rod 34 is connected to the gripping head 36 that is positioned exterior to the chamber defined by the membrane 32. The rod 34 extends from the opening such that the gripping head 36 is spaced outwardly from the opening defined by the membrane 32. The elongated member 20 can be of such a length that it extends beyond the second end of the struts when the implantable 10 occupies an expanded position. When the gripping head 36 is spaced from the proximal ends of the struts and the membrane 32, a removal device (not shown) can easily grip the exposed gripping head 36. In alternative embodiments, the rod 34 terminates to form the gripping head 36 positioned inwardly of the opening defined by the member 32. Other embodiments of the gripping head 36 can include various changes in shape and size of the gripping head 36 to cooperate with different coupling mechanisms.

The elongated member 20 can also be of such a length that the elongated member 20 and the struts 30 extend substantially the same distance from the connecting mechanism 16 when the implantable device 10 is in a fully collapsed state (not shown). The struts 30 can lie flat along the rod 34 for a low profile configuration. The gripping head 36 preferably remains exposed so that the implantable device 10 can be pushed out of a delivery instrument by conveniently applying a force to the gripping head 36.

A variety of removal devices can be used to engage the implantable device to, for example, reposition, re-implant, or remove the implantable device as discussed above. The enlarged gripping head 36 can be designed to facilitate removal of the implantable device 10 by any of numerous extracting devices and methods as are known in the art. The removal gripping head 36 can be gripped by a removal device (such as forceps, an extractor, a retractor, gripping device, or other suitable device for gripping a portion of the implantable device 10). A sufficient proximal force can be applied to displace the implanted implantable device 10 from the implantation site. The illustrated gripping head 36 is a somewhat cylindrical knob having an outer diameter that is greater than the outer diameter of the rod 34. The gripping head 36 can have other configurations for engaging a removal device. Exemplary gripping heads can comprise a hook, ring, enlarged portion, connectors (e.g., snap connector, threaded connector, etc), or other structure for permanently or temporarily coupling to a removal device.

FIG. 2 is a side view of an embodiment of an implantable device 50. The obstruction member 58 is coupled with the anchor 56 by a connecting mechanism 52. In the illustrated embodiment, the connecting mechanism 52 comprises a connecting member 54. The connecting mechanism 52 permits

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articulation between the obstruction member 58 and the anchor 56. In the illustrated position, the obstruction member 58 and the anchor 56 are collinear along the longitudinal axis of the implantable device 50. Through articulation of the connecting mechanism 52, the obstruction member 58 and the anchor 56 can be configured to no longer be collinear along the longitudinal axis of the implantable device 50. As one non-limiting example, the obstruction member 58 can be maintained at an unaltered orientation while the connecting mechanism 52, either by pivoting or flexing, can continue to couple the obstruction member 58 to the anchor 56 while the anchor 56 is moved to a different orientation than that of the obstruction member 58. In some embodiments, the connecting mechanism 52 can permit axial movement, changing the distance between the distal end of the obstruction member 58 and the proximal end of the anchor 56. In some embodiments, the articulation of the connecting mechanism 52 is accomplished through discrete pivotal orientation changes. In other embodiments, the connecting mechanism 52 is configured to articulate through continuous flexing, such as the bending of a flexible member. In still other embodiments, the connecting mechanism 52 can be configured to permit changes in orientation between the obstruction member 58 and the anchor 56 by limiting separation between the obstruction member 58 and the anchor 56 when the connecting mechanism 52 is not rigidly coupled to the two components. In these embodiments, the connecting mechanism 52 can comprise a tether or other limiting component.

FIG. 3 is a cross-sectional view of another embodiment of an implantable device 100. The implantable device 100 is configured to permit an angled position. The implantable device 100 can be positioned in a naturally angled air passageway (e.g., a bifurcated air passageway, tortuous air passageway, etc.) in a lung. The implantable device 100 has an anchor sufficiently articulable so as to permit deployment of the implantable device 100 within the angled air passageway without substantially altering the natural geometry of the air passageway. The implantable device 100 can effectively function even though the obstructing member 102 conforms to the natural shape of the air passageway. The implantable device 100 can be generally similar to the implantable device 10 of FIG. 1, and accordingly, the following description of the implantable device 100 can equally apply to the implantable devices described below, unless indicated otherwise.

As used herein, the term "implantable device" is a broad term and is used in its ordinary meaning and includes, without limitation, articulated implantable devices, actuatable implantable devices, and other implantable devices that have one or more means for providing articulation, actuating, or flexibility between an anchor and a functional member, such as an obstruction member. The implantable devices may have any number of pivot points or flexible portions. These implantable devices can be placed along tortuous pathways, such as a section of a lung passageway that is substantially curved along its length. Some embodiments include a means for providing flexibility that comprises any combination of a biasing member, a flexible member, a ball and socket arrangement, a joint, a linkage, a hinge, and/or a flexible connector. As such, the flexible implantable device can be selectively curved or angled along its length to match the shape of the air passageway.

The illustrated implantable device 100 comprises an obstructing member 102 articulably and pivotally connected to an anchor system 104. The anchor system 104 can be moved relative to the obstructing member 102 to a desired position depending on the functional application of the device 100. An articulating connecting portion 106 connects and

permits movement between the obstructing member **102** and the anchor system **104**. The articulating connecting portion **106** permits articulation of the device **100** such that the device **100** can be implanted in curved air passageways without significantly altering the natural geometry of the air passageway. For example, the implantable device **100** can span a bronchial branching section of a lung. The implantable device **100** can be articulated repeatedly (e.g., during normal lung functioning) without appreciable trauma to the lung, or to the implantable device **100**. Traditional stent-based devices for implantation in air passageways are typically rigid elongated structures that are not suitable for placement in bifurcated or substantially curved air passageways. These stent-based devices maintain their linear configuration thus rendering them unsuitable for use in these types of air passageways.

With reference again to FIG. 3, the articulating connecting portion **106** can have various configurations for permitting relative movement between the anchor system **104** and the obstructing member **102**. In some embodiments, including the illustrated embodiment, the articulating connecting portion **106** comprises at least one ball and socket arrangement. The illustrated anchor system **104** has an anchor socket **120** comprising a generally spherical cavity that holds one end of the connecting rod **124**, while the obstructing member **102** has an obstructing socket **122** that holds the other end of the connecting rod **124**.

The connecting rod **124** has a first end **128** and an opposing second end **126**. Each of the ends **126**, **128** is generally spheroidal and sized to be received by the corresponding socket **122**, **120**. The spheroidal shape the ends **126**, **128** can be integral with the connecting rod **124** or generally spheroidal-shaped members can be coupled to or mounted on the ends **126**, **128**. The first end **128** is rotatably mounted in the obstructing socket **122**. The second end **126** is rotatably mounted in the anchor socket **120**. As such, the sockets **120**, **122** can rotate freely about the ends of the connecting rod **124**. Thus, the implantable device **100** has a plurality of joints that permit articulation. The implantable device can have any number of articulable connecting portions for a particular application.

To reduce wear of the balls and the sockets, the surface(s) of the sockets and/or ends **126**, **128** can be coated with a material to reduce frictional interaction. For example, the interior surface **130** of the anchor socket **120** can comprise one or more of the following: a somewhat lubricious material (e.g., Teflon®), ceramics, metals, polymers (preferably hard polymers), or combinations thereof. However, other materials can be utilized to limit or inhibit wear between the connecting rod **124** and the obstructing member **102** and/or the anchor system **104**. When the implantable device **100** is deployed in the lungs, the anchor socket **120** can move, preferably slightly, with respect to the ball at the second end **126** during normal respiration. The wear-resistant surfaces can minimize debris build up that can impede performance of the implantable device **100**. In view of the present disclosure, one of ordinary skill in the art can determine the appropriate combination of materials, geometry of the ball and socket arrangement, and the length of the connecting rod **124** to achieve the desired positioning of the implantable device **100**.

The connecting rod **124** can have a one-piece or multi-piece construction. In some embodiments, the connecting rod body **142** and the ends **126**, **128** are formed of a single material (e.g., a metal such as Nitinol or titanium). In other embodiments, the connecting rod body **142** is formed of a flexible material, and the ends **126**, **128** are formed of a somewhat hard, rigid material, such as a ceramic.

The connecting rod **124** can be generally straight, as shown in FIG. 3. However, the connecting rod **124** can have other configurations based on clinical need. For example, the connecting rod **124** of FIG. 8 has an angled shape that allows placement of the implantable device in a complex shaped airway (e.g., an airway with sharp curves, branching portions, etc.).

With continued reference to FIG. 3, an elongated member **134** includes a rod **138** having an end portion **140** that is connected to the obstructing member frame **136**. The end portion **140** can be connected to the frame **136** by one or more mechanical fasteners, adhesives, welding, bonding, interference fit, threads, or other suitable coupling means for securely coupling the rod **138** to the frame **136**. In some embodiments, including the illustrated embodiment, the rod **138** is connected to the interior portions of the struts **110**, although the rod can be connected to other portions of the frame **136**. The rod **138** can also be formed integrally with at least a part of the frame.

As shown in FIG. 4, the implantable device **150** can be placed at a branching air passageway of the bronchial tree. The obstructing member **152** is within a proximal passageway **160** and the anchor system **154** is positioned within a distal sub-branch air passageway **162**. The implantable device **150** can therefore span the junction **164** of the air passageway of the lung and, thus, permits flexibility in positioning of the device **150**. The air passageway can generally retain its natural shape, such as its shape before implantation of the implantable device **150**, to minimize trauma to the lung tissue. The orientations of the implantable devices are not limited solely to the illustrated orientations. The implantable device **150** can be reversed from the illustrated orientation so that the anchors are located proximally of the obstructing member. Thus, the implantable device **150** can be oriented to permit air flow in any desired direction.

The implantable device **150** can also be implanted in non-branching portions of lungs. If desired, the implantable device **150** can be implanted in continuous air passageways that are generally straight, curved, angled, or having any other configuration. Because the implantable device **150** can assume various configurations, there is significant flexibility in selecting a deployment site. The implantable device **150** can also be implanted in air passageways that have a substantially constant or varying cross-section. Advantageously, the physician can implant the implantable device **150** at various locations throughout the lung to treat specific portions of the lung. If the implantable devices are in the form of occluding devices or flow regulating devices (e.g., a one-way valve, flow resistor, etc.), these devices can be implanted proximally of, and adjacent to, the diseased portions of a lung, thus maximizing the amount of healthy lung tissue that can function, even if the diseased lung tissue is in the far distal portions of the bronchial tree.

FIG. 5 illustrates an implantable device **200** that comprises an anchor system **202** that is pivotally coupled to an elongated member **204** that extends through the obstructing member **206**. The elongated member **204** has a generally spheroidal member **208** that is rotatably mounted in an anchor socket **210** of the anchor system **202**. The obstructing member **206** can be fixedly attached at some point along the elongated member **204**.

To secure the obstructing member **206** to the elongated member **204**, a portion of an obstructing member frame **212** and/or a membrane **214** can be coupled to the elongated member **204**. In the illustrated embodiment, the struts of the

obstructing member frame **212** and the membrane **214** are both coupled to the outer surface of the elongated member **204**.

Once deployed, the implantable device **200** illustrated in FIG. **5** can be retained in place by the anchor system **202**. The implantable device **200** can be positioned in a non-linear lumen, such as those illustrated in FIG. **4**, because the anchor system **202** may remain at a first orientation while the obstructing member **206** is pivoted to a second orientation by the generally spheroidal member **208** and the anchor socket **210**. The obstructing member **206** can be configured to move axially from the anchor system **202** through travel along the elongated member **204**, which can be limited to prevent inefficient operation of the implantable device **200**.

FIG. **6** is a cross-sectional view of a implantable device **250** that has an articulable connecting portion **252** that permits axial movement between an anchor system **254** and an obstructing member **256**. The connecting portion **252** includes a holder **260** of the anchor system **254** and a holder **262** of the obstruction member **256**. Each of the holders **260**, **262** is configured to receive an end of a connector **264**. The illustrated connector **264** has enlarged ends that are held by the holders **260**, **262**. The chambers **268**, **278** of the holders **260**, **262**, respectively, permit axial movement of the connector **264**. The enlarged ends of the connector **264** that are held by the holders **260**, **262** can also be constructed to permit pivotal movement in addition to axial movement.

The anchor system **254** and the obstructing member **256** of the device **250** can move freely towards and away from each other. However, one or more biasing members (not shown) can be positioned between the anchor system and obstructing member of the implantable device to adjust positioning of the implantable device. The biasing member can cooperate with the connecting portion to ensure that the implantable device remains in a desired position.

FIG. **7** illustrates an implantable device **300** that has an articulating connecting portion **302** that includes a flexible member **304** connected to the anchor system **306** and the obstructing member **308**. The flexible member **304** can comprise a somewhat flexible elongated member (e.g., a solid rod, a hollow tube, ribbon, etc.) and can comprise metal, polymers (preferably a somewhat rigid polymer), filaments, and the like. The flexible member **304** preferably does not substantially stretch or buckle when an axial force is applied thereto. Alternatively, the flexible member **304** can be configured to allow significant axial movement between the anchor system **306** and the obstructing member **308**. The flexible member **304** can be, for example, a tether that holds together and limits the axial movement of the anchor system **306** away from the obstructing member **308**. However, the flexible member **304** may be easily collapsed as the anchor system **306** is moved towards the obstructing member **308**. The flexible member **304** can comprise a rope, wire, filaments, or other suitable member for providing relative movement between the anchor system **306** and the obstructing member **308**.

With reference to FIG. **8**, the connecting rod **350** can have or bend to have an angled central portion **352** that defines an angle  $\theta$ . The length **L1** and **L2** can be selected to achieve the desired orientation and size of an implantable device. If the implantable device is deployed at a sharp bend of an air passageway, the angle  $\theta$  can be matched with the angle of the bend to generally align the longitudinal axis of an anchor system with one of the passages and the longitudinal axis of an obstructing member with the other passage. The implantable device, for example, can include a connecting rod for deployment in air passageways that together form an acute

angle. Accordingly, the configuration of the connecting rod **350** can be selected based on the target deployment site.

As illustrated in FIG. **9**, the implantable device **400** can have a biasing member **402** positioned between an obstructing member **404** and an anchor system **406**. One example of such a biasing member is a helical spring. In the illustrated embodiment, a tether **408** extends through the biasing member **402** between the obstructing member **404** and the anchor system **406**. Other embodiments can have a tether **408** connecting the obstructing member **404** and an anchor system **406** that does not extend through the biasing member **402** and instead passes at least partially outside the biasing member **402**. Alternatively, a flexible cylindrical member (not shown) can extend between the obstructing member **404** and the anchor system **406**, substantially completely enclosing the biasing member **402**. The tether can also be a connector such as the one illustrated in FIG. **7**.

FIGS. **10A-10C** illustrate various embodiments of support frames of implantable devices, each having a means for flexing. Each of the support frames has a flexible connecting portion that permits relative movement between an anchor system and an obstructing member frame. The frames as illustrated do not have membranes; however, any of various types of membranes can be applied to the obstructing member frames. FIG. **10A** illustrates a frame support **450A** that includes a flexible connecting portion **452A** in the form of slots in an alternating pattern. The connecting portion **452A** can be an integral piece with the frame, as illustrated, or can be coupled or mounted to an anchor system **454A** and an obstruction frame **456A**. The flexible connecting portion **452A** can be formed by cutting slots out of a tube. The number and size of the slots can be selected to achieve the desired flexibility. Additionally, the material used to construct the connecting portion can be selected for its flexibility characteristics.

FIG. **10B** illustrates a frame support **500B** that is generally similar to the frame support **450A** of FIG. **10A**. In the illustrated embodiment, the frame support **500B** includes a flexible connecting portion **502B** in the form of a spring member extending axially along the longitudinal axis of the frame support **500B**. As such, the spring member can be arranged in a spiral fashion about the longitudinal axis of the flexible connecting portion **502B**. The illustrated spring member is in the form of a helical spring, although other types of springs or resilient members can be utilized. The spring can comprise the connecting member alone or can act as a biasing member, as described above. Additionally, as described above, the spring can be formed integrally with the frame, or serve as a coupler for both an anchor system and obstruction frame.

FIG. **10C** illustrates a frame support **550C** that comprises a flexible connecting portion **552C** comprising a mesh. The connecting portion **552C** can comprise a mesh of various sizes, with large or small mesh spaces. Additionally, the mesh can be constructed of a variety of materials, such as metals, synthetics, or any other resilient material. The mesh can permit flexing, as when the obstructing frame **554C** and anchor system **556C** are positioned at different orientations, as described above. In some embodiments, the mesh can also permit axial compression along the longitudinal axis of the frame support **550C**. As described, the mesh can be formed integrally with the frame, or be mounted or coupled at either end to the obstructing frame **554C** and anchor system **556C**.

The illustrated struts **600A**, **600B**, **600C** of FIGS. **10A-10C** each have two generally elongated straight portions connected by a bend. The struts **600A**, **600B**, **600C** can also have a continuously curved configuration similar to the struts described above. The frame supports can carry a membrane to

form an obstructing member, such as an obstructing member adapted to function as a valve (preferably a one-way valve). The connecting portions can enhance the seating of the obstructing member within an air passageway to enhance valve functioning.

With reference to FIG. 11, an implantable device 700 is illustrated as having a flexible connecting portion 702, such as the one shown in FIG. 10A. The implantable device 700 is deployed and implanted in an air passageway 708 and is held in place by its anchor system 704. The flexible connecting portion 702 can apply a force to the obstructing member 706 of the implantable device 700 to enhance seating between the membrane of the obstructing member 706 and the wall 708. Thus, a bias of the flexible connecting portion 702 can ensure that an effective seal is maintained between the obstructing member 706 and the wall 708, thereby limiting or preventing the flow of air distally past the implantable device 700. Advantageously, the implantable device 700 can permit the passage of air proximally past the obstructing member 706 when the pressure differential across the implantable device 700 is sufficiently high. As the air flows proximally past the obstructing member 706, the flexible connecting portion 702 can apply a distally directed force. When the pressure differential is reduced a sufficient amount, the obstructing member 706 is pulled distally against the air passageway wall 708 to once again form a seal with the air passageway wall. Thus, the obstructing member 706 can move slightly during normal lung functioning while the anchor system 704 can remain securely fixed in place. The flexible connecting portion 702 can therefore enhance the valving action of the implantable device 700.

If desired, the connecting portion 702 can also be used to position the anchors 704 and the obstructing member 706 along a tortuous path within a lung, as shown in FIG. 4 above. The connecting portion 702 can be positioned along sharp turns that may be unsuitable for rigid valves, such as stent-based devices.

All patents and publications mentioned herein are hereby incorporated by reference in their entireties. Except as further described herein, the embodiments, features, systems, devices, materials, methods and techniques described herein may, in some embodiments, be similar to any one or more of the embodiments, features, systems, devices, materials, methods and techniques described in U.S. patent application Ser. No. 10/409,785 (U.S. Publication 2004-0200484), filed Apr. 8, 2003; Ser. No. 09/951,105 (U.S. Publication No. 2003/0050648A1), filed Mar. 13, 2003; Ser. No. 10/848,571, filed May 17, 2004; Ser. No. 10/847,554, filed May 17, 2004; Ser. No. 10/418,929, filed Apr. 17, 2003; Ser. No. 10/081,712 (U.S. Publication 2002-0112729), filed Feb. 21, 2002; Ser. No. 10/178,073 (U.S. Publication 2003-0154988), filed Jun. 21, 2002; Ser. No. 10/317,667 (U.S. Publication 2003-0158515), filed Dec. 11, 2002; Ser. No. 10/103,487 (U.S. Publication 2003-0181922), filed Mar. 20, 2002; Ser. No. 10/124,790 (U.S. Publication 2003-0195385), filed Apr. 16, 2002; Ser. No. 10/143,353 (U.S. Publication 2003-0212412), filed Mar. 9, 2002; Ser. No. 10/150,547 (U.S. Publication 2003/0216769), filed May 17, 2002; Ser. No. 10/196,513 (U.S. Publication 2004-0010204), filed Jul. 15, 2002; Ser. No. 10/254,392 (U.S. Publication 2004/0059263), filed Sep. 24, 2002; Ser. No. 10/387,963 (U.S. Publication 2004-0210248), filed Mar. 12, 2003; Ser. No. 10/745,401, filed Dec. 22, 2003; U.S. Pat. Nos. 6,293,951; 6,258,100; 6,722,360; 6,592,594, which are hereby incorporated herein and made part of this specification. In addition, the embodiments, features, systems, devices, materials, methods and techniques described herein may, in certain embodiments, be

applied to or used in connection with any one or more of the embodiments, features, systems, devices, materials, methods and techniques disclosed in the above-mentioned incorporated applications and patents.

The articles disclosed herein may be formed through any suitable means. The various methods and techniques described above provide a number of ways to carry out the invention. Of course, it is to be understood that not necessarily all objectives or advantages described may be achieved in accordance with any particular embodiment described herein. Thus, for example, those skilled in the art will recognize that the methods may be performed in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other objectives or advantages as may be taught or suggested herein.

Furthermore, the skilled artisan will recognize the interchangeability of various features from different embodiments disclosed herein. Similarly, the various features and steps discussed above, as well as other known equivalents for each such feature or step, can be mixed and matched by one of ordinary skill in this art to perform methods in accordance with principles described herein. Additionally, the methods which are described and illustrated herein are not limited to the exact sequence of acts described, nor are they necessarily limited to the practice of all of the acts set forth. Other sequences of events or acts, or less than all of the events, or simultaneous occurrence of the events, may be utilized in practicing the embodiments of the invention.

Although the invention has been disclosed in the context of certain embodiments and examples, it will be understood by those skilled in the art that the invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses and obvious modifications and equivalents thereof. Accordingly, the invention is not intended to be limited by the specific disclosures of preferred embodiments herein.

What is claimed is:

1. An implantable device configured to be secured within an air passageway, the device comprising:
  - a distal portion comprising an anchor system and a longitudinal axis, the anchor system comprising at least one piercing tip and being configured to engage tissue of an air passageway wall;
  - a proximal portion; and
  - a flexible portion connecting the distal portion to the proximal portion, the flexible portion being configured such that the distal portion can articulate substantially with respect to the proximal portion such that the distal portion and the proximal portion are non-collinear along the longitudinal axis of the distal portion.
2. The device of claim 1, wherein the proximal portion has a larger diameter than the distal portion.
3. The device of claim 1, wherein the distal portion, the proximal portion, and the flexible portion are all formed in a single piece.
4. The device of claim 1, wherein the at least one piercing tip comprises a planar member configured to limit advancement of the at least one piercing tip into the tissue of the air passageway wall.
5. The device of claim 1, wherein the at least one piercing tip is atraumatic.
6. The device of claim 1, wherein the anchor system comprises a plurality of piercing tips extending radially outward relative to the longitudinal axis of the distal portion.
7. The device of claim 1, wherein the flexible portion is hollow.



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8. The device of claim 1, wherein the flexible portion comprises a rigid rod portion.

9. The device of claim 8, wherein the rigid rod portion extends through an axial center of a helical spring.

10. The device of claim 1, wherein the flexible portion comprises a tube or cylindrical member having one or more slots.

11. The device of claim 1, wherein the flexible portion comprises a spring member extending in a longitudinal axial direction.

12. The device of claim 1, wherein the flexible portion comprises a flexible mesh.

13. The device of claim 1, wherein the proximal portion comprises a frame member.

14. The device of claim 13, wherein the frame member comprises one or more struts.

15. The device of claim 13, further comprising a membrane portion disposed over at least a portion of the frame member.

16. The device of claim 1, wherein the device is collapsible for containment within a delivery catheter.

17. The device of claim 1 further comprising an elongate member with a proximal end and a distal end, the elongate member being attached at its distal end to the proximal portion or the distal portion.

18. The device of claim 17, wherein the elongate member is configured to be engaged by a removal tool for repositioning or removal of the device.

19. The device of claim 17, wherein the elongate member comprises a knob at its proximal end.

20. A system for inserting a pulmonary device into an air passageway of a lung, the system comprising:

a catheter; and

a pulmonary device configured to be inserted into a distal end of the catheter, the pulmonary device comprising:

a proximal portion;

a distal portion comprising a longitudinal axis and at least one anchor configured to secure the pulmonary device within the air passageway, and

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a connecting member coupling the proximal portion and the distal portion and allowing the longitudinal axis of the distal portion to be non-collinear with the proximal portion.

21. The system of claim 20, wherein the proximal portion comprises a frame member.

22. The system of claim 21, wherein the frame member comprises a plurality of struts.

23. The system of claim 22, wherein the plurality of struts extend in a longitudinal direction and form a bell or umbrella shape, and wherein the plurality of struts are connected to each other at a first distal end.

24. The system of claim 23, wherein the plurality of struts have a second proximal end curving inward toward the longitudinal axis.

25. The system of claim 21, wherein a membrane covers at least a portion of the frame member.

26. The system of claim 20, wherein the proximal portion comprises a proximal rod extending along a longitudinal axis of the proximal portion.

27. The system of claim 26, further comprising a removal tool configured to engage the proximal rod.

28. The system of claim 20, wherein the pulmonary device is in an at least partly collapsed configuration when inserted into the distal end of the catheter.

29. The system of claim 20, wherein the connecting member comprises a tube or cylindrical member with one or more slots.

30. The system of claim 20, wherein the connecting member comprises a spring.

31. The system of claim 20, wherein the connecting member comprises a mesh.

32. The system of claim 20, wherein the connecting member comprises a rigid rod connected to one or more pivot points or flexible portions.

33. The system of claim 32, wherein the pivot point or flexible portion comprises at least one ball and socket assembly.

34. The system of claim 32 further comprising a spring member arranged along an axis of the rigid rod.

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